# Trinity Health Of New England

# Humanitarian Use Device Informed Consent Form

**[Note, this is a sample document that may not cover all nuances for various devices. You may add, delete and / or edit sections to make them applicable to the device being used.] Please delete this statement on the final consent form.**

**Principal Physician:**

**Physician’s Phone Number:**

**Title of the Device:**

**Name of Recipient:**

**[Instructions]**

* ***[DELETE all items in [ ] from the final document.***
* ***The consent document must be written in lay language.***
* ***Use lay language to explain medical concepts. If a medical term is used follow it by a lay explanation.***
* ***Keep sentences short.***
* ***The use of bulleted lists and/or tables may be helpful.***
* ***Unless otherwise noted all of the sections listed above and below are required.***
* ***Unless otherwise noted the text within each section may be revised to be appropriate to the specific HUD for which approval is sought.***
* ***Requiring the subject to initial on the bottom of each page is optional.***
* ***All pages must leave a bottom margin of 1 inch to allow for IRB stamps.***
* ***If needed, revise the second page number in the footer (i.e. 1 of 2,3, or 4) to reflect the appropriate total number of pages.***
* ***Font size must be a minimal of 12 point but may be larger and should be font that is easy to read, e.g. times new roman.***
* ***Make the final document all one color.***
* ***Include a version reference in the footer of the consent form.]***

*The new Common Rule has issued some new guidance as it relates to informed consent. It is now required that a concise summary of the research be included at the beginning of each consent form.* ***Please do not repeat the language from the summary in other sections below, but instead expand and clearly state what the subject will be doing in more detail. [After Reading please remove this information from your consent form.****]*

**This is a type of Humanitarian Use Device (HUD) This HUD includes only patients who choose to take part. This consent form explains the purpose of this medical device and your involvement. Please read it carefully and take as much time as you need. Please take your time to make your decision. Your participation is voluntary.**

**You are being asked to take part in this Humanitarian Use Device (HUD) because you have** *type of Condition/Disease***.**

**[Summary of the Humanitarian Use Device (HUD) including purpose duration, and list of procedures].**

**There are risks to the Humanitarian Use Device (HUD) that are described later in this consent form. Some of the risks include: [list the risks here].**

**There are benefits to participating in the Humanitarian Use Device (HUD) and described later in this consent form. Some of the benefits include: [list the benefits here].**

***[Alternative procedures or course of treatment, if any*]**

**If you are interested in learning more about this Humanitarian Use Device (HUD), please continue reading the information below.**

**What should you know about Humanitarian Use Devices (HUDs)?**

A Humanitarian Use Device (HUD) is a medical device. The Food and Drug Administration (FDA) determines if a device is an HUD. To receive FDA approval as a HUD the device must meet the following conditions:

* the device is expected to benefit fewer than 4,000 people in the United States per year;
* no comparable device, other than another HUD or a device still undergoing research, is available to treat or diagnose the condition.

Because the device is anticipated to benefit only a small group of people, complete information about the safety and effectiveness of the device is not known. The FDA has approved use of the device because the information that is available suggests that the device will not expose you to a significant risk of illness or injury.

To use an HUD the physician must also get the approval of the local Institutional Review Board (IRB). The IRB is responsible for protecting participant’s rights. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 860-714-4068.

**What is the name of the HUD that will be used?**

You are being asked to allow the use of a HUD called *[insert name of HUD].* The FDA has approved the use of [*insert name of HUD]* to provide treatment for patients who have problems with [*insert name of disease or injury]* and who have failed other treatments. You are eligible to use [*name of HUD]* because you have [*name of disease or injury]* and you have not improved with available treatments.

Through discussion and this document, we will explain to you how the device will be used. Please ask questions at any time about anything you do not understand. Please read this form carefully and take as much time as you need in deciding whether to let the doctors use the HUD.

**What will happen if you agree to the use of the HUD?**

If you agree to the use of [*insert name of HUD]*, you will:

* *[Describe the procedure in detail chronologically using lay language, short sentences, and short paragraphs.*

**What are the risks of using the HUD?**

The HUD has not been proven effective for this use.

*[Identify the risks of using the HUD and of any procedures required for its use. Include in the description of risks warnings listed on the product labeling. In addition to physiological risks/discomforts, if appropriate, describe psychological, social, and legal risks that might result.]*

*[If appropriate to the procedure, end with the statement:]* There may be side effects and discomforts that are not yet known.

**During your participation, you will be notified of newly discovered side effects which may affect your health or willingness to participate.  You may be asked to sign a new consent form that shows that you have been informed of new information relating to this Humanitarian Use Device (HUD).**

**Are there benefits from the use of the HUD?**

*[State the direct or possible benefit from the use of the HUD, if any.]*

**During your participation, you will be notified of newly discovered significant findings.  You may be asked to sign a new consent form that shows that you have been informed of new information relating to this Humanitarian Use Device (HUD).**

What are and what will Happen with my Bio-specimens?

Bio-specimen are samples that are collected through urine, blood, tissues, cells, Deoxyribonucleic acid (DNA), Ribonucleic acid(RNA), and protein from your body. *[Please note if your Humanitarian Use Device (HUD)* *requires Bio-Specimens please provide an explanation of what Bio-specimens are in Layman’s Terms.]*

*De-identified information or bio-specimens may be used in future research studies without additional informed consent.*

Or

*Identified information or bio-specimens may be used in future research studies without additional informed consent.*

*[Include the following statement for research involving biospecimens:]*

1. **Your [*Biopsecimen*] may be used for commercial profit and you [*will/will not*] share in this profit.**
2. **You will/will not be informed of your [Biopsecimen] results.**
3. **Your [*Biopsecimen*] [*will/will not*] include whole genome sequencing.**

**Will it cost you anything to use the HUD?**

**Taking part in this Humanitarian Use Device (HUD) may lead to added costs to you or your insurance company, and any costs not covered by your insurance will be your responsibility.**

**Trinity Health Of New England sites may not be financially responsible for costs associated with this Humanitarian Use Device (HUD). Please ask about any expected added costs or insurance problems.**

**Please choose from one of the options below:**

**Option 1:**

“The Sponsor will responsible for the payment of this additional care.”

**Option 2:**

“The Sponsor will not be responsible for the payment of this additional care.  The research participant or their insurance company will be responsible for the payment of this additional care.”

**Option 3:**

**“**You or your insurance company will be charged for continuing medical care and/or hospitalization.”

If your insurance company will not pay for the procedure or the device, you will be responsible for these costs. If your insurance company will pay for only a portion of the procedure or the device, you will be responsible for the costs that insurance does not cover. Your doctor will contact your insurance company to see if they will pay for the device. If you have to pay in full, the estimated cost for the device is $XXX and related medical charges are estimated to be $XXX

**Will you be paid for using the HUD?**

You will not be paid for receiving the device.

**Can you decide not to allow the use of the HUD?**

You may withdraw your consent to have the device used at any time. For example, if you consent today for a procedure scheduled for tomorrow, you can still change your mind tomorrow. [If the device cannot be removed once it has been used include language to that effect, or if it can be removed, provide a brief description of what that would entail.]

**What are the options if you do not want to use the HUD?**

*[Describe alternatives other HUDs or investigational devices that are available that should be considered before deciding whether or not to use this HUD. If there are no alternatives, state that an alternative is to not allow the use of the HUD. Avoid suggesting that participation is the only way to obtain medical care.]*

You do not have to agree to the use of [*insert name of HUD].* If you do not agree, you will continue to receive standard care for your condition. Your care at a Trinity Health Of New England site will not be adversely affected if you choose not to receive the HUD. If your insurance does not pay, or you do not have insurance, you will be responsible for the costs.

There is currently no other approved device available to treat your condition. There is one other device approved as an HUD for this condition. [Provide a brief description of the other device.]

**Who will pay for treatment if you are injured as a result of the use of the HUD?**

**In the case of injury or illness resulting from this Humanitarian Use Device (HUD), emergency medical treatment is available but will be provided at the usual charge.** *[The following sentence is required by the Institution for projects involving more than minimal risk]:* **If you sustain injuries from your participation in this Humanitarian Use Device (HUD), you may not be compensated by Trinity Health Of New England.**

**Please choose from one of the options below:**

**Option 1:**

“The Sponsor will responsible for the payment of this additional care.”

**Option 2:**

“The Sponsor will not be responsible for the payment of this additional care.  The research participant or their insurance company will be responsible for the payment of this additional care.”

**Option 3:**

**“**You or your insurance company will be charged for continuing medical care and/or hospitalization.”

If you are injured as a result of the use of *[insert name of HUD]*, your insurance company will be billed for the costs of treatment. Neither Trinity Health Of New England sites, nor the FDA, nor the government has any program that would pay the costs for the use of [*insert name of HUD].or for the treatment of any complications of the procedures required for the use of* [*insert name of HUD].*

**What other things should you know?**

**a. Whom should you call if you have questions about the device?**

Call the principal physician, Dr. \_\_\_\_\_\_\_ at *[insert telephone number.]*

# **b. What should you do if you have a device-related problem?**

 If you have an urgent medical problem related to the use of the HUD, call [*designated physician]* at [*phone or beeper number available 24 hours.]*

If you think you are injured or ill as a result of the use of the HUD, call the principal investigator, Dr. \_\_\_\_\_\_\_\_, at [*insert telephone number.]*

The medical services at a Trinity Health Of New England site will be available to you as they are to all sick or injured individuals. Trinity Health Of New England sites do not have a program to pay you if you are hurt or have other bad results from receiving this device. You are financially responsible for payment of any treatment or hospitalization. At your request, your insurance provider will be billed for payment of any treatment or hospitalization.

**What does your signature mean?**

By signing this consent form you are not giving up any legal rights. Your signature means 1) that you have had information about the HUD explained to you, 2) that you have been given the opportunity to ask questions and 3) that you accept the provisions in this form, and you agree to receive the HUD.

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Patient’s Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient’s Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Individual Obtaining Consent

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Individual Obtaining Consent Date

**NOTE:** A copy of the signed and dated consent form must be kept by the principal physician, a copy must be given to the patient, and a copy must be placed in the patient’s record.